How Do I Submit a Human Subject Research Project to the Durham VAMC?

1. Ensure you have a valid VA Appointment

You must have a VA appointment to conduct VA research. To be a Principal Investigator (PI), you must be either VA paid, without compensation (WOC), or appointed or detailed to VA under the Intergovernmental Personnel Act (IPA) of 1970.

Trainees: Only students and other trainees (including residents and fellows) from schools with an academic affiliation agreement consistent with current VHA policy may serve as investigators (but not as PIs) within a VA facility or use data or human biological specimens that have been collected within VA for clinical, administrative, or research purposes. A VA investigator sufficiently experienced in the area of the trainee's research interest must serve as PI and is responsible for oversight of the research and trainee.

Contact Nancy Dixon in the Research Office if you have questions about WOC status: Nancy.Dixon5@va.gov or 919-286-6926.

2. Complete Mandatory Research Training

In addition to VA education requirements, Research has one mandatory course for all research personnel:

- VA Human Subjects Protection & Good Clinical Practices: This training is required every three years (https://www.citiprogram.org).

Depending on what your protocol requires (handling or shipping hazardous agents/specimens) or whether you will work in a research laboratory, you may need additional training. Contact Lester Nichols at Lester.Nichols@va.gov at 919-286-0411 x 7341 for more information.

3. Maintain a Research Scope of Practice

All individuals who participate in research at the Durham VAMC must have an approved Research Scope of Practice that specifically defines their research roles and responsibilities. Personnel may have only the research roles and responsibilities, as defined by their approved Scope of Practice and approved by their direct supervisor, which are appropriate to their level of training, specific license, and clinical credentials. Submit a new SOP if there are any changes to research responsibilities. Submit a Research Scope of Practice PI Update if adding or changing supervising investigators.

4. Write a Research Protocol and Abstract

- Protocol: The protocol must contain all elements as required in the Research SOP RI 802, Research Protocol. Two protocols may need to be submitted—the main protocol and a local protocol that is Durham specific for the procedures / research that will be done at the Durham VAMC as part of the study.
  See the "Durham VAMC Protocol Guidance" document for more information.

- Abstract: Abstracts should be one page long with no special characters. The abstract should include the Purpose, Methodology, and Objectives.

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5. Consider if Research May Be Exempt from IRB Review

Research activities in which the only involvement of human subjects will be in one or more of the categories below may be exempt from the provisions of the Common Rule. Contact the Research Office for more information.

- Research conducted in established or commonly accepted educational settings, involving normal educational practices.
- Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.
- Research involving the collection or study of existing (i.e., on the shelf, already collected, and/or banked prior to the date the study is to start) data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- Taste and food quality evaluation and consumer acceptance studies.

Note that if the research is exempt from IRB review, R&D Committee review is required.

In addition to the Exemption Application, these documents/forms are also required as part of the Exempt Research Submission:

- Protocol, Abstract, Request to Review/Investigator Overview form, IRB Submission Checklist, Page 18 / Investigator Data (if new PI), Resume (if new PI) Conflict of Interest Form, PO/ISO Review Checklist (this should be completed and sent to the ISO and PO prior to IRB submission), Staff Listing, Research Scope of Practice (for PI and each person on the Staff List), and evidence of completing all required VA research training.

If the research is not exempt from IRB Review:

6. Determine how you wish to Screen and Recruit

Most studies will pre-screen potential participants (either by using clinic data, data from CPRS/VistA, etc.). If you wish to do screen and recruit by looking at patient records before getting the patient's informed consent and HIPAA authorization, you must have a waiver of informed consent to screen and recruit and a waiver of HIPAA authorization to screen and recruit.

See Appendix A, "Informed Consent and HIPAA Authorization Guidance" for additional information.

7. Determine Appropriate Method of Informed Consent

Determine if the research requires 1) documented informed consent 2) a waiver of documentation of informed consent, or 3) complete waiver of informed consent.

- Documented Informed Consent: Most prospective research will require an informed consent *process* where the potential subject becomes informed about

the research and makes a thoughtful determination to participate, continue participation, or decline participation in a research study. This process is documented by a written informed consent form (ICF) signed and dated by the subject and the person obtaining informed consent. All research consent forms must be reviewed and approved by the IRB prior to using to consent a subject.

- Waiver of Documentation of Informed Consent: In this scenario, a consent process occurs but the subject does not sign a written consent form. The consent process may be verbal (over the phone) or evidenced by the fact that the subject returned a mailed questionnaire, completes an online questionnaire, etc. You must request and receive approval from the IRB for a waiver of documented consent; you must also apply for a HIPAA waiver of authorization. The IRB may require the PI to provide the subject with a written statement regarding the research.

  Criteria for Waiver of Documentation of Informed consent are as follows:
  - The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether s/he wants documentation linking the him/her with the research, and the subject's wishes will govern; **or**
  - That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

- Waiver of Informed Consent: In this scenario, no consent process occurs. This process is usually reserved for retrospective studies. You must request and receive approval from the IRB to waive the informed consent process; you must also apply for a HIPAA waiver of authorization to screen, recruit, and conduct the research.

  Criteria for Waiver of Informed Consent in Minimal Risk Research are as follows:
  - Research involves no more than minimal risk to the subjects; **and**
  - Waiver or alteration will not adversely affect the rights and welfare of the subjects; **and**
  - Research could not practicably be carried out without the waiver or alteration; **and**
  - Whenever appropriate, the subjects are provided with additional pertinent information after participation.

See Appendix A, "Informed Consent and HIPAA Authorization Guidance" for additional information.

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8. Determine the Appropriate HIPAA Authorization
Determine if the research requires a 1) signed HIPAA authorization from the research subject 2) a HIPAA waiver to screen and recruit, or 3) a HIPAA waiver to screen, recruit, and conduct.

- A HIPAA Authorization documents the subject's permission for his/her identifiable health information to be used and/or disclosed for a research purpose. If the research requires a written informed consent form, a HIPAA authorization is also required. The language in the protocol, ICF, and HIPAA authorization should be consistent.

See Appendix A, "Informed Consent and HIPAA Authorization Guidance" for additional information.

8. Complete all Required Initial Submission Forms
See: http://www.durham.va.gov/research/initial_review/Initial_Review.asp OR S:\Research Forms Jan 09\HUMAN FORMS Dec 08\Initial Review Forms

These forms must be completed for initial review submissions:

- **IRB Submission Checklist:** This checklist must be submitted with your initial application and can be used as a guide, as it outlines all the forms/documents you'll need to complete/create.

- **Page 18:** Page 18 is required for new Principal Investigators (PIs) or Co-Investigators only. If the PI has submitted a Page 18 for a prior study, do not re-submit. PIs must be VA faculty (full time, part time, or WOC). Medical residents, fellows, pharmacy students, and nursing students must contact the Research Office prior to a protocol submission.
    - A VA Investigator sufficiently experienced in the area of the trainee's research interest must serve as PI or co-PI and is responsible for oversight of the research and the trainee. The PI or co-PI is responsible for ensuring the trainee complies with all applicable local, VA and other federal requirements.
    - A resume or CV is also required for all new Investigators.

- **Request to Review / Investigator Overview:** Funding source must be included (write 4 digit number and sponsor name). Once funded, you must notify the Research Office. This form must be signed by the Section/Service Chief or it will not be submitted to the IRB for review. Complete all applicable items.

- **Abstract:** The abstract is mandatory. Abstracts should only be one page long with no special characters. The abstract should include the Purpose, Methodology, and Objectives.

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- **Protocol:** The protocol must contain all elements as required in the Research SOP RI 802, Research Protocol. Note: Two protocols may need to be submitted—the main protocol and a local protocol that is Durham specific for the procedures/research that will be done at the Durham VAMC as part of the study.

- **Grant Application:** If applicable, a copy of the grant must be submitted regardless of funding source.

- **Informed Consent:** If applicable, the informed consent form should be drafted using the VA Form 10-1086 template and must contain elements of informed consent as required in the Research SOP IC 701, General Requirements and Documentation of Informed Consent. If requesting a waiver of documented informed consent, submit the "Waiver of Informed Consent Documentation" form. If requesting a waiver of consent (to screen and recruit or to screen, recruit, and conduct the study), include a "Waiver or Alteration of the Informed Consent Process."

- **HIPAA Authorization:** You must include a HIPAA authorization form or a "Waiver or Alteration of HIPAA Authorization."

- **Staff Listing:** A completed Staff Listing must be submitted for initial review. The Staff Listing provides a list of all personnel who conduct any part of the research endeavor and must include the names of all individuals either involved in the conduct of the study or who make decision regarding study procedures.

- **Conflict of Interest (COI) Statement:** All Investigators (including Co- and Sub-Investigators) must complete this form and must obtain signature from the Principal Investigator. The COI survey must also be updated if there are any COI changes during the course of the study.

- **Privacy, Confidentiality, and Information Security Checklist:** The Privacy Officer and Information Security Officer reviews should occur **prior** to IRB submission. The Checklist and supporting documentation should be completed, signed by the PI, and submitted electronically to the PO and ISO at the same time. **Do not** submit your application to the IRB until you have made all corrections and have signed PO and ISO approval.

- **Appendix G:** Complete this form to indicate whether or not the study involves biological, chemical, physical, or radiation hazards.

- If not already on file with the Research Office, submit current CITI and any other required training certificates for all personnel involved with the research project.

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- If not already on file with the Research Office, submit a Research Scope of Practice document for all personnel involved with the research project. Ensure that the PI reviews each individual's Research Scope of Practice. The PI should indicate approval by signing and dating the form.
    - If an individual has a current Research Scope of Practice but is assigned to work with a PI that is not listed on his/her current Research Scope of Practice, the individual must complete a Scope of Practice PI Update Form and submit the form to the Research Office.

- Include the following as applicable:
    - Investigator's Brochure and/or Package insert
    - Form 10-9012 (required for drug studies)
    - All questionnaires that will be given to subjects for completion
    - Typed telephone script
    - Recruitment letters
    - Advertisements (flyers, radio or newspaper adds, etc.)
    - Declaration of HIPAA De-Identification
    - Application to Establish a Research Data Repository
    - Research Data Repository Written Procedures for Operations
    - Application to Use Data from a Data Repository
    - Standard Operating Procedure (SOP) for Using Human Blood or Tissue
    - Recombinant DNA Form
    - Viral Vector Form
    - Training Documentation to Pack/Ship Biological Specimens
    - Department of Defense (DoD) forms
    - Department of Education (ED) forms

9. Receive Information Security Officer (ISO) and Privacy Officer (PO) Review and Approval

Submit the protocol, ISO/PO Checklist, informed consent document, and HIPAA forms (or ICF and HIPAA waiver documentation) to the ISO and PO for review and approval prior to submitting the initial review package to the IRB. The IRB requires the ISO/PO Checklist with both ISO and PO approval signatures. Submit documents electronically to Jeffrey.Gardiner@va.gov and Jennifer.Runnals@va.gov.

The ISO and PO will work with you until your research protocol/consent/HIPAA forms are acceptable. For more information, see the "Privacy and Information Security Review of Research Protocols" document available on the research website.

10. Submit the application package to the Research Office

The Research Office is located on the first floor of Building 8. Timestamp the submission, make a copy of the submission for your research records, and place the submission package in the inbox located in the lobby of the Research Building.
The Research Office will conduct a preliminary review of your submission package and will route your submission for appropriate review, including review by the:

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- Institutional Review Board
- Subcommittee for Research Safety (if applicable)
- Research and Development Committee
- Associate Chief of Staff for Research and Development

Once the appropriate committees have reviewed your research project, you will receive communication from our Research Office with more instruction.

Please contact Hayley White, Human Research Protection Program Coordinator, at extension 4726 or at Hayley.White2@va.gov with questions.

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Background Information

Research with human subjects requires IRB review and approval before the research may commence.

What is VA Research?
Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

A research project is designated as "VA research" if it meets any of the following criteria:

1. The project is supported by VA funds, or funds are administered by the non-profit Institute for Medical Research, Inc. (IMR).
2. Study personnel identify and/or enroll human subjects, obtain informed consent, or carry out research procedures utilizing VA resources (e.g., VA time, facilities, space, personnel, equipment, or CPRS).
3. VA paid employees, employees appointed to work without compensation (WOC), or an employee assigned to VA through the Intergovernmental Personnel Act (IPA) of 1970 work on the project as part of their official duties at the VA or during a designated VA tour of duty.

What are Human Subjects?
A *Human subject* is a living individual about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information

Private information must be individually identifiable to constitute research involving human subjects (identity of the subject is or may readily be ascertained by the investigator or associated with the information).

Private information/specimens are not individually identifiable if:

- They are not collected specifically for the currently proposed research; **-AND-**
- Investigators cannot *readily* ascertain the identity of the individuals to whom the coded private information/specimens pertain because of prohibitions to release of the key to the code (e.g., agreement, IRB-approved policy, legal requirements)

Please contact Hayley White, Human Research Protection Program Coordinator, at extension 4726 or at Hayley.White2@va.gov with questions.

Appendix A: Informed Consent and HIPAA Authorization Guidance

What do you want to do?[1]	**Screen and/or Recruit** Screen/recruit potential participants without obtaining their informed consent to view their medical records.	**Consent in Person** Conduct a study where you will see participant face to face to determine interest in the research study.	**Consent Without Obtaining a Signature** Conduct a phone survey or an online or mailed survey / questionnaire.	**No Consent Process** Retrospective chart review or other scenarios where there is no participant contact.
What this means	No consent process or HIPAA authorization to screen/recruit, but you will seek informed consent (and possibly HIPAA authorization) prior to enrolling the participant into the research study.	You will need to use a written informed consent form and a written HIPAA authorization. You will obtain the participant's signature on both documents.	You will need an informed consent script that contains the elements of informed consent, but you do not obtain the participant's signature. You will request to waive HIPAA authorization.	There is no consent process or HIPAA authorization.
What kind of approval does this need?	ICF: Waiver to screen and/or recruit	ICF: Written informed consent form	ICF: Informed consent script **AND** a Waiver of Documentation of Informed Consent	ICF: Waiver of informed consent
		If you want to waive or alter some consent elements, you'll need approval to waive/alter consent		
	HIPAA: Waiver to screen and/or recruit	HIPAA: A written HIPAA authorization	HIPAA: Waiver of HIPAA authorization	HIPAA: Waiver of HIPAA authorization
		If you want to waive or alter some HIPAA elements, you'll need approval to waive/alter HIPAA		
Complete these forms	ICF: Waiver or Alteration of the Informed Consent Process[2]	ICF: Durham VAMC ICF template	ICF: 1) Use the Durham ICF template as guide for the script, **and** 2) Waiver of Documentation of Informed Consent	ICF: Waiver or Alteration of the Informed Consent Process[2]
		If you want to waive/alter elements of informed consent: Waiver or Alteration of the Informed Consent Process[2]		
	HIPAA: Waiver or Alteration of HIPAA Authorization[2]	HIPAA: Durham VAMC HIPAA template	HIPAA: Waiver or Alteration of HIPAA Authorization[2]	HIPAA: Waiver or Alteration of HIPAA Authorization[2]
		If you want to waive/alter HIPAA: Waiver or Alteration of HIPAA Authorization[2]		

[1] You can choose more than one option (e.g., you may screen/recruit and also obtain a written or verbal informed consent)

[2] You can make multiple requests on the Waiver or Alteration requests (e.g., you can request a waiver to screen/recruit and alter the elements of informed consent and/or HIPAA)